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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,134	10/15/2001	Bradford Evan Gliner	337348021US	4196

25096 7590 03/15/2004

PERKINS COIE LLP
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER

BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
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3762

10

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,134

Applicant(s)

GLINER ET AL.

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, drawn to a neuro-stimulation system, classified in class 607, subclass 45.
 - II. Claims 15-31, drawn to a method of automatically determining a favorable neuro-stimulation program for a patient, classified in class 607, subclass 45.
 - III. Claims 32-40, drawn to a method of automatically determining a favorable neuro-stimulation program for a patient, classified in class 607, subclass 59.
 - IV. Claim 41, drawn to a method of automatically determining a favorable neuro-stimulation program for a patient, classified in class 607, subclass 46.
 - V. Claim 42, drawn to a method of automatically determining a favorable neuro-stimulation program for a patient, classified in class 607, subclass 66.
 - VI. Claims 43-49, drawn to a method of automatically determining a favorable neuro-stimulation program for a patient, classified in class 607, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II-VI (process) and I (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus such as requiring only analog circuitry.

3. Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require choosing a configuration of therapy electrodes and/or an electrical stimulus corresponding to a sensed response. The subcombination has separate utility such as not requiring storing the effective therapy electrode configuration and/or electrical pulse in a memory of the controller, but rather immediately applying the effective therapy.

4. Inventions IV and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require

determining whether the response is within a desired range or an improvement over a previous sensed response from a different electrical stimulus and/or a different configuration of therapy electrodes. The subcombination has separate utility such as not requiring selecting a setup configuration of therapy electrodes and a control stimulus of electrical parameters, but rather having a preselected configuration of therapy electrodes.

5. Inventions V and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require selecting an alternate configuration of therapy electrodes and/or an alternate electrical stimulus. The subcombination has separate utility such as not requiring reapplying the adjusted stimulus parameters to the setup configuration of therapy electrodes and sensing a response signal using the sensing device, but rather using different stimulus parameters.

6. Inventions II and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the

particulars of the subcombination as claimed because the combination does not require applying a sub-threshold electrical stimulus to the configuration of therapy electrodes, the sub-threshold electrical stimulus having a current intensity less than the current intensity of the threshold electrical stimulus. The subcombination has separate utility such as not requiring selecting an alternate configuration of therapy electrodes and/or an alternate electrical stimulus, but rather using the same configuration.

7. Inventions IV and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require sending a command signal from a controller to a pulse system operatively coupled to the controller. The subcombination has separate utility such as not requiring selecting a setup configuration of therapy electrodes and a control stimulus of electrical parameters, but rather having a preselected configuration of therapy electrodes.

8. Inventions V and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require

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sending a command signal from a controller to a pulse system operatively coupled to the controller. The subcombination has separate utility such as not requiring reapplying the adjusted stimulus parameters to the setup configuration of therapy electrodes and sensing a response signal using the sensing device, but rather using different stimulus parameters.

9. Inventions III and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require applying a sub-threshold electrical stimulus to the configuration of therapy electrodes, the sub-threshold electrical stimulus having a current intensity less than the current intensity of the threshold electrical stimulus. The subcombination has separate utility such as not requiring storing the effective therapy electrode configuration and/or electrical pulse in a memory of the controller, but rather immediately applying the effective therapy.

10. Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the

particulars of the subcombination as claimed because the combination does not require applying an electrical stimulus having a plurality of stimulus parameters to a control configuration of therapy electrodes. The subcombination has separate utility such as not requiring selecting a setup configuration of therapy electrodes and a control stimulus of electrical parameters, but rather having a preselected configuration of therapy electrodes.

11. Inventions IV and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require applying a sub-threshold electrical stimulus to the configuration of therapy electrodes, the sub-threshold electrical stimulus having a current intensity less than the current intensity of the threshold electrical stimulus. The subcombination has separate utility such as not requiring selecting a setup configuration of therapy electrodes and a control stimulus of electrical parameters, but rather having a preselected configuration of therapy electrodes.

12. Inventions V and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP §

806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require applying a sub-threshold electrical stimulus to the configuration of therapy electrodes, the sub-threshold electrical stimulus having a current intensity less than the current intensity of the threshold electrical stimulus. The subcombination has separate utility such as not requiring reapplying the adjusted stimulus parameters to the setup configuration of therapy electrodes and sensing a response signal using the sensing device, but rather using different stimulus parameters.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

14. A telephone call was made to Paul Parker on March 11, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


R.B.



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700